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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/554,387 06/29/00 FABRY

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023657 HM12/0226  
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EXAMINER

JIANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

02/26/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/554,387

Applicant(s)

FABRY, BERND

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This application claims the foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed herein on June 29, 2000.

### ***Election/Restrictions***

Applicant's response to species election requirement in Paper No. 8, submitted January 8, 2001 is acknowledged. The traversal is found persuasive. The requirement is therefore withdrawn. Claims 11-30 will be examined on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-12, 20-22, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Jandacek (3,865,939; PTO-1449 submitted June 29, 2000).

Jandacek discloses that phytosterols (synonymously phytostenols) have significant hypocholesterolemic activities. Jandacek also discloses that phytosterols such as  $\beta$ -sitosterol ( $\beta$ -sitostenol) along with unsaturated fatty acids having from 6 to 18 carbon atoms or glycerides of such fatty acids within the instant claims in an effective amount or combined with foodstuffs are useful for reducing serum cholesterol content in a mammal. See col.1 lines 5-14, col.2 lines 1-5, col.3 lines 27-28, col.4 lines 41-44,

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Table I, col.5 lines 17-31, Example I and claims 1, 3 and 6. Thus, Jandacek anticipates Claims 11-12, 20-22, and 30.

Claims 11-12, 17, 20-22, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hasegawa et al. (XP 002099834; PTO-1449 submitted June 29, 2000).

Hasegawa et al. teaches linoleic acid and/or phytosterol including sitosterol (sitostenol) are useful for lowering the serum cholesterol in human mammals. Hasegawa et al. also teaches the vegetable oils have hypocholesteremic effects since they are high in linoleic acid and sitosterol. See the abstract. Thus, Hasegawa et al. anticipates Claims 11-12, 17, 20-22, and 27.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-16, 18-19, 23-26 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939; PTO-1449 submitted June 29, 2000) and Hasegawa et al. (XP 002099834; PTO-1449 submitted June 29, 2000) in view of Miettinen et al. (EP 0594612B1; PTO-1449 submitted June 29, 2000), and Hidvegi (5,277,910).

Jandacek discloses that phytosterols (synonymously phytostenols) have significant hypocholesterolemic activities. Jandacek also discloses that phytosterols such as  $\beta$ -sitosterol (synonymously  $\beta$ -sitostenol) along with unsaturated fatty acids having from 6 to 18 carbon atoms or glycerides of such fatty acids within the instant claimed compounds in an effective amount or combined with foodstuffs are useful for reducing serum cholesterol content in a mammal. See col.1 lines 5-14, col.2 lines 1-5, col.3 lines 27-28, col.4 lines 41-44, Table I, col.5 lines 17-31, Example I and claims 1, 3 and 6. Jandacek further teaches that the concentration level of phytosterols and unsaturated fatty acids having 6 to 18 carbon atoms in the hypocholesterolemic composition should be about 2.0 to about 6.0 wt.% and 0.5 to 15 wt.%, respectively, within the instant claims. See claim 1 and col.5 lines 17-23.

Hasegawa et al. teaches linoleic acid and/or phytosterol including sitosterol (sitostenol) are useful for lowering the serum cholesterol in human mammals. Hasegawa et al. also teaches the vegetable oils have hypocholesteremic effects since they are high in linoleic acid and sitosterol. See the abstract.

Jandacek and Hasegawa et al. do not expressly disclose the carboxylic acid of a phytostenol (phytosterol) ester or a  $\beta$ -sitosterol ( $\beta$ -sitostenol) having from 2 to 22 carbon atoms and up to about 3 double bonds. Further, Jandacek and Hasegawa et al. do not expressly disclose that the composition is encapsulated in gelatin.

Miettinen et al. teaches that  $\beta$ -sitosterol ( $\beta$ -sitostenol) and  $\beta$ -sitostanol and their fatty acid esters are known to be useful to lower serum cholesterol levels. See page 2 lines 5-7 and claim 1. Miettinen et al. further teaches that usable fatty acids therein

contain approx. 2-22 carbon atoms such as fatty acids in vegetable oil i.e., rapeseed oil within the instant claims. It is well known that rapeseed oil contains about 90% unsaturated fatty acids having one or more double bonds. See page 3 lines 44-45 and Example 1 on page 4.

Hidvegi discloses a pharmaceutical composition for lowering the blood-lipid level containing sitosterol and fatty acids such as linoleic acid formulated into gelatin capsules. See col.1 lines 59-65, col.2 line 37, col.3 line 38 and col.8 lines 18-28.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to select a particular carboxylic acid of a phytostenol (phytosterol) ester or a  $\beta$ -sitosterol ( $\beta$ -sitostenol) having from 2 to 22 carbon atoms and up to about 3 double bonds for use in methods of reducing serum cholesterol content and to make the composition encapsulated in gelatin.

One having ordinary skill in the art at the time the invention was made would have been motivated to select a particular carboxylic acid of a phytostenol (phytosterol) ester or a  $\beta$ -sitosterol ( $\beta$ -sitostenol) having from 2 to 22 carbon atoms and up to about 3 double bonds for use in methods of reducing serum cholesterol content because it is known that particular  $\beta$ -sitosterol ( $\beta$ -sitostenol) fatty acid ester or  $\beta$ -sitostanol fatty acid esters having from 2 to 22 carbon atoms and up to about 3 double bonds are useful for lowering serum cholesterol levels according to Miettinen et al. teaching. Additionally, one of ordinary skill in the art would have been motivated to make the composition encapsulated in gelatin since the known pharmaceutical composition of Hidvegi for

lowering the blood-lipid level containing sitosterol and fatty acids such as linoleic acid herein is formulated into gelatin capsules.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

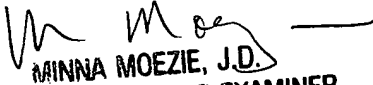
In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
February 23, 2001

  
MINNA MOEZIE, J.D.  
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